DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
g1880d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 18, 2001

John F. Wells
President
Wells Johnson Company
8000 South Kolb Road
P.O. Box 18230
Tucson, AZ 85731

PINL-02-2

Dear Mr. Wells:

The Food and Drug Administration (FDA) conducted an inspection of your firm's medical device facility located in Tucson, Arizona. The inspection covered your general and plastic surgery devices. Profile classes ELE, PRF, and MTL were covered.

At the end of the inspection, the FDA investigator left a list of inspectional observations (Form FDA 483, dated September 13, 2001) at your firm. We have received your firm's written response, dated September 25, 2001 to the Form FDA 483. Copies of this response and the Form FDA 483 are enclosed.

While this inspection found deficiencies of your quality system that would warrant a warning letter if not corrected, your written response has satisfied us that you either have taken or are taking appropriate corrective actions. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations, and initiating permanent corrective actions. At this time, FDA does not intend to take further action based on these inspectional findings.

Our office recognizes the unusual circumstance that your firm is currently the subject of Chapter 11 Bankruptcy and fully under the control of the United States Bankruptcy Court for the District of Arizona with respect to financial activities. We also understand that your company has significantly reduced the number of your employees and suspended a number of your operations. We recognize that your company must submit cost projections to the Court, therefore, final closure to all observations are dependant on the Court's approval of expenditures. A follow-up inspection will be required, however to

ensure that the corrections are adequate. Please advise our office when you fully resume your firm's activities in order this reinspection can be scheduled. The agency is relying on your commitment regarding corrective actions and, should we later observe that the deviations from the quality system regulation have not been remedied, future regulatory action (e.g., seizure, injunction and/or civil penalties) may be taken without further notice.

Based upon your corrective action, the deficiencies noted during FDA's inspection will not affect applicable pending premarket submissions or export certificates for devices manufactured at your facility that were specifically inspected. This information is available to Federal agencies when they consider awarding contracts.

There may be other devices and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address the quality system regulation in these areas.

Your firm has an ongoing responsibility to conduct internal self-audits to assure you are continuing to maintain conformance with the quality system regulation.

For further information, please contact FDA Senior Compliance Officer, Dannie E. Rowland at (949) 798-7649.

Sincerely,

Alonza Cruse
Los Angeles District Director

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